

Guidance for Industry

Guide to Minimize Microbial Food Safety Hazards of Leafy Greens

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

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Guidance for Industry¹

Guide to Minimize Microbial Food Safety Hazards for Leafy Greens

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This guidance is intended to assist domestic firms and foreign firms exporting leafy greens into the United States (U.S.) by recommending practices to minimize the microbial food safety hazards of the products throughout the entire leafy greens supply chain. It identifies some, but not all, of the preventive measures that these firms may take to minimize these food safety hazards. This guidance document is not intended to serve as an action plan for any specific operation, but should be viewed as a starting point. We encourage each firm from the farm level through the retail or foodservice level to assess the recommendations in this guidance and then tailor its food safety practices to its particular operations by developing its own food safety programs based on the assessment of the potential hazards and its operations.

In addition, effective management of food safety requires that responsibility be clearly established among the many parties involved in the production of fresh produce. There may be many different permutations of ownership and business arrangements during the growing, harvesting packing, processing and distribution of fresh and fresh-cut leafy greens. For this reason, it is important to identify which responsibilities rest with which parties, and to ensure that these responsibilities are clearly defined. For example, growers commonly contract with third parties to harvest their crops. It also is important that growers clearly identify which party is responsible for each applicable provision of this guidance, such as providing adequate toilet and handwashing facilities and worker training. Approaches to addressing responsibilities include delegating them to individuals within the firm and formally addressing them in contractual agreements when third parties are involved. Each party should be aware of its responsibilities to ensure microbial food safety hazards for leafy greens are minimized at each stage of the supply chain.

This guidance is intended to supplement existing guidances, including the [“Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”](#) (October 1998) (Good Agricultural Practices or GAPs Guide) and the [“Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables”](#) (February 2008) (Fresh-cut Guide), which apply to fresh produce. The GAPs Guide provides recommendations for growers, packers, and shippers to use good agricultural practices

¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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in those areas over which they have control to prevent or minimize microbial food safety hazards in fresh produce. The Fresh-cut Guide provides recommendations to fresh-cut produce processing firms to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards in fresh-cut processing operations. The information included in this leafy greens-specific guidance is consistent with recommendations provided in the GAPs Guide and the Fresh-cut Guide.

This guidance also specifically refers to FDA's regulations in 21 CFR part 1, subpart J on the establishment, maintenance, and availability of records and 21 CFR part 110 on current good manufacturing practices in manufacturing, packing, or holding human food. The recommendations in this guidance complement, but do not supersede, the requirements in those regulations and any associated recommendations. Further, the recommendations in this guidance do not affect the applicability of any other Federal or State requirements and your responsibility to comply with them.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

From 1996 to 2008, eighty-two foodborne illness outbreaks were associated with the consumption of fresh produce. Of these produce-related outbreaks, 28 (34.1%) were linked to the consumption of leafy greens. During this time period, leafy greens-associated outbreaks accounted for 949 illnesses and 5 deaths. The foodborne illnesses in most (85.7 percent) of these outbreaks were caused by *Escherichia coli* (*E. coli*) O157:H7. *Cyclospora* and *Salmonella* also have been the cause of outbreaks linked to leafy greens (Ref. 1). Many factors may play a role in the incidence and reporting of foodborne illness outbreaks that implicate fresh produce, such as an aging population that is susceptible to foodborne illness; an increase in global trade; a more complex supply chain; improved surveillance and detection of foodborne illness; improvements in epidemiological investigation; and increasingly better methods to identify pathogens (Refs. 2-6).

In 1998, to improve the safety of fresh produce, FDA issued its GAPs Guide. The GAPs Guide provides general food safety guidance on the production and packing of fresh produce for critical production steps where food safety might be compromised during the growing, harvesting, transportation, cooling, packing, and storage of fresh produce. More specifically, the GAPs Guide alerts fruit and vegetable growers, packers, and shippers to the potential microbiological hazards associated with various aspects of the production chain including: land history; near-by land use; water quality; worker health and hygiene; pesticide and fertilizer use; equipment cleaning and sanitation; and product transportation. Since its issuance, the GAPs Guide has been widely accepted.

In 2004, FDA issued its [“Produce Safety from Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption”](#) (Action Plan) to minimize further foodborne illness associated with the consumption of fresh produce. This Action Plan incorporated "lessons learned" in implementing the GAPs Guide and expanded upon other existing produce safety efforts. There are four

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general objectives set out in the Action Plan: (1) prevent contamination of fresh produce; (2) minimize the public health impact when contamination occurs; (3) improve communication between all parties; and (4) facilitate research relevant to the contamination of fresh produce. For each objective, the plan identifies steps or actions that could contribute to the achievement of the objectives.

Many of the steps set out in the Action Plan are relevant to the goal of reducing foodborne illness caused by *E. coli* O157:H7 and other pathogens associated with leafy greens. One such step was to provide technical assistance to industry in their efforts to develop commodity specific guidelines. On April 25, 2006, a coalition of associations representing the industry issued the “[Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain](#)” (2006 industry guidelines) (Ref. 7). The 2006 industry guidelines provide voluntary recommendations on food safety practices that are intended to minimize the microbiological hazards associated with fresh and fresh-cut leafy greens. The leafy greens industry has since updated and supplemented its 2006 industry guidelines with additional recommendations on the production and harvest of leafy greens that include quantitative metrics and other measures to assist industry in implementing the guidelines (Ref. 8). The 2006 industry guidelines and subsequent updates, as well as other programs and experience, serve as the basis for this guidance. FDA conducted its own review of the provisions of the industry guidelines and made decisions to incorporate, modify, or exclude specific aspects of those guidelines based on the agency’s evaluations. The industry guidelines, which identify specific metrics for certain recommended practices that are not included in this guidance, may provide a useful additional resource for parties involved in the production and harvest of leafy greens; however, FDA is not responsible for the content of the guidelines, which FDA has not verified.

FDA will continue to evaluate how best to measure the extent to which the recommendations in this and other federal guidance, as well as industry standards and practices, are being implemented and are effective in reducing microbial contamination in leafy greens. In particular, we are considering the extent to which more specific measures, including metrics, should be utilized to help verify the implementation and efficacy of the federal recommendations and industry practices. We are also evaluating the extent to which metrics can be applied to diverse geographic areas within the United States and internationally.

Another step in FDA's Action Plan was the multi-year [Leafy Greens Safety Initiative](#) (Initiative) that began in 2006. The first year of this Initiative focused on lettuce ([Lettuce Safety Initiative](#)) as a response to recurring outbreaks of *E. coli* O157:H7 associated with fresh and fresh-cut lettuce. FDA and the California Department of Public Health continued these efforts in 2007 with a focus on a broader range of leafy greens, including spinach, building upon lessons learned in the first year, subsequent outbreak investigations, and FDA’s [Tomato Safety Initiative](#). The Initiative is part of a risk-based strategy to reduce foodborne illness by focusing food safety efforts on specific products, practices, and growing areas that have been found to be problematic in the past. As the multi-year initiative continues, findings will be used to direct education/outreach and research efforts. Findings will also be incorporated into this guidance as appropriate.

In 2007, the [California Leafy Greens Products Handler Marketing Agreement](#) (LGMA) was initiated providing a mechanism for verifying through government audits that leafy greens farmers in California follow certain food safety practices in the production and harvest of leafy greens. The LGMA incorporates a set of industry best practices titled “[Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens](#),” a quantitative food safety model for firms to use in the production and harvesting of leafy greens. (Ref. 8) (A similar LGMA program was also initiated in Arizona in late 2007). Operators

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producing and harvesting leafy greens may find useful the LGMA best practices document consisting of quantitative food safety measures. Please note that although FDA provided technical assistance in the development of the document, it is not responsible for the content of the document, which FDA has not verified.

In late 2007, USDA's Agricultural Marketing Service (AMS) sought comments via an advance notice of proposed rulemaking on the possibility of a Federal marketing program to regulate the handling of leafy greens throughout the country. As described in a Federal Register notice published on October 4, 2007 (72 FR 56678), AMS is considering, among other options, the implementation of a marketing agreement to reduce the risk of pathogenic contamination during the production and handling of leafy greens. In further response to the 2007 notice, on June 8, 2009, a coalition of produce associations submitted a proposal to AMS requesting the establishment of a national marketing agreement for leafy greens based on the model used in the California and Arizona programs.

On March 20 and April 13, 2007, FDA held two public hearings to seek comments and to discuss safer practices for growing, harvesting, packing, cooling, and shipping of fresh produce, including leafy greens. The information received is being used to inform the Agency's decisions regarding next steps (72 FR 8750, February 27, 2007). On August 22, 2008, FDA published a final rule in the Federal Register amending the food additive regulations to provide for the safe use of ionizing radiation for control of foodborne pathogens, and extension of shelf-life, in fresh iceberg lettuce and spinach (73 FR 49593).

FDA also has been actively engaged in developing international standards of hygienic practices for fresh leafy green vegetables. FDA is leading the effort to draft the Fresh Leafy Vegetables Annex to the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables.

The Agency is issuing this commodity specific supply chain draft guidance for leafy greens, which is drawn primarily from the 2006 industry guidelines, along with agency experience and information from other recent public and private programs. This FDA guidance supplements existing, but broader, recommendations in FDA's GAPs Guide and Fresh-cut Guide. Developing this guidance is one step among others that the Agency may take to minimize the microbiological hazards associated with fresh and fresh-cut leafy greens.

III. Scope and Use

This guidance covers leafy greens that are grown, harvested, and then packed or cooled for fresh market or for "fresh-cut/value-added processing" (i.e., minimally processed, such as chopped or shredded, moved through a series of washes, and then bagged or pre-packaged), shipped to food service or retail establishments and offered for sale to the consumer. Such leafy greens may be grown in and harvested from open fields, shade houses or greenhouses. The use of the term "leafy greens" in this document includes raw agricultural commodities and fresh-cut/value-added products. Examples of leafy greens include iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard. Leafy greens do not include herbs such as cilantro and parsley.

This guidance addresses microbiological hazards that may be associated with fresh and fresh-cut leafy greens

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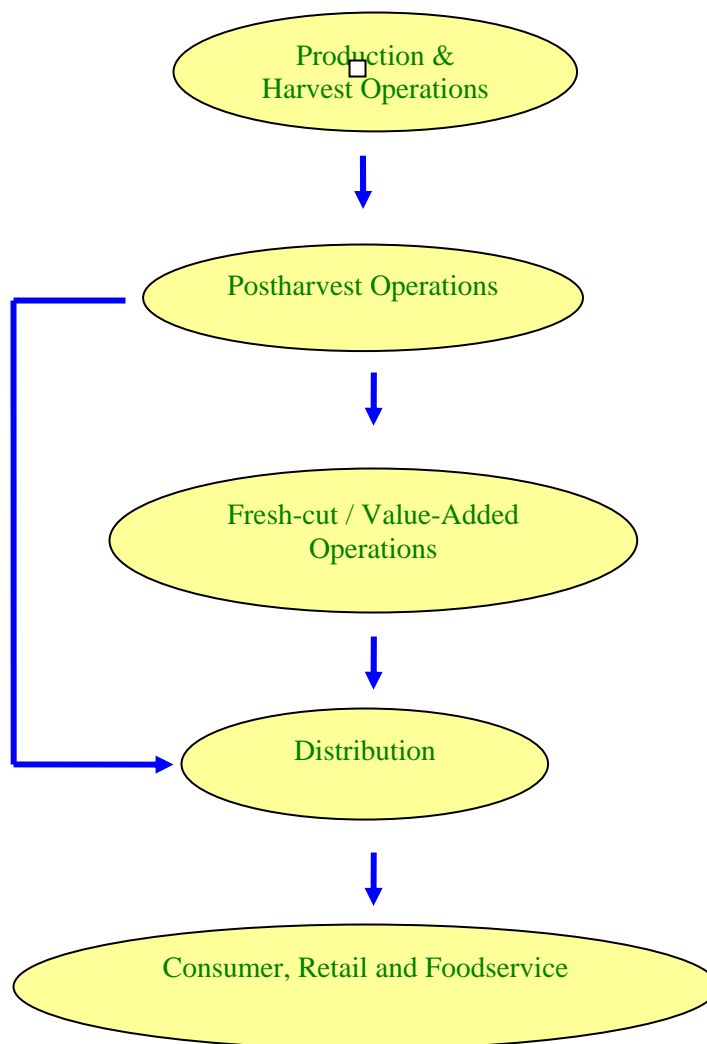
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produce and appropriate control measures for such hazards. It does not specifically address chemical hazards. Consistent with the GAPs Guide and Fresh-cut Guide, this guidance emphasizes the importance of employing prevention rather than elimination strategies to address microbiological hazards. Once fresh produce has been contaminated, removing or killing the microbial pathogens while maintaining the fresh attribute of the produce is very difficult. Prevention of microbial contamination at all steps in the field-to-fork continuum is preferable to treatment to eliminate contamination after it has occurred.

Although this guidance to industry does not specifically include a section for consumers, it is critical that consumers also handle fresh produce safely and not contaminate it. Consumers may refer to [“Safe Handling of Raw Produce and Fresh-Squeezed Fruit and Vegetable Juices.”](#)

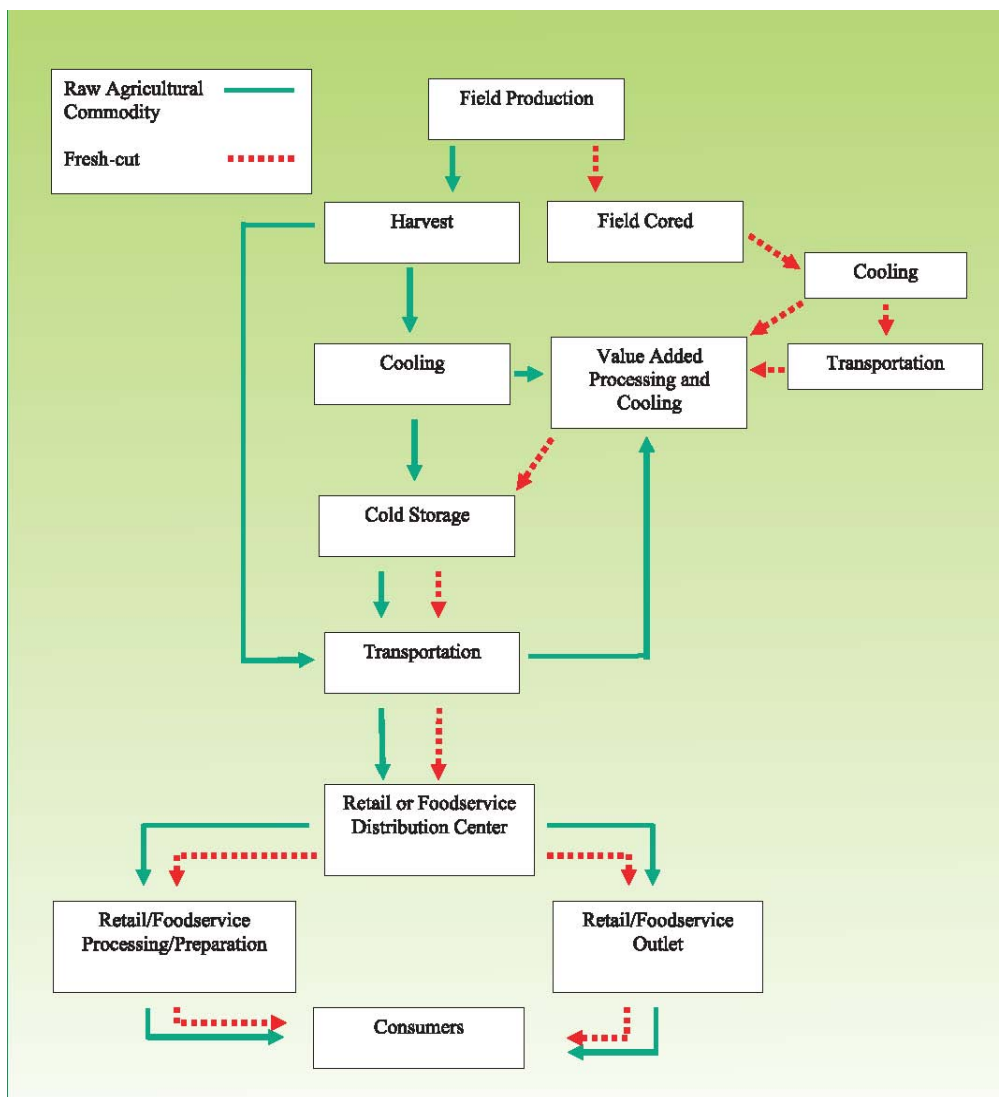
In the sections that follow, the leafy greens field-to-fork continuum has been broken down into the following: (1) production and harvest operations; (2) postharvest operations; (3) fresh-cut/value-added operations; (4) distribution; and (5) consumer, retail and foodservice (Figure 1). A diagram of the supply flow through these unit operations is provided in Figure 2. Within each operation, general recommendations regarding issues relevant to that operation are made to raise awareness and allow individuals and firms involved in the field-to-fork continuum to consider actions that are appropriate to their operations. The identified issues in each section focus only on leafy greens, as defined above, and may or may not apply to other specialty crops. Firms are encouraged to use this guidance to evaluate their operations and develop their own individual company food safety programs.

Figure 1. Leafy Greens Unit Operations



Description: The leafy greens field-to-fork continuum can be broken down into the following unit operations: (1) production and harvest operations; (2) postharvest operations; (3) fresh-cut/value-added operations; (4) distribution; and (5) consumer, retail and foodservice. Note: Figure 1 is reprinted from the “Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain” (Ref. 7). Reprinted with permission.

Figure 2. General Supply Chain Flow for Leafy Greens



Description: This diagram depicts the general route leafy greens take from field production to consumers. Leafy greens are marketed as either a raw agricultural commodity, as indicated by the solid arrow, or a fresh-cut product, as indicated by the dotted arrow. As raw agricultural commodities, leafy greens may go directly from field production and harvest to transportation and the retail chain, or they may go through the following steps: harvest, cooling, cold storage, transportation, retail or foodservice distribution center, retail/foodservice outlet or retail/foodservice/processing/ preparation, and consumers. Fresh-cut leafy greens may go straight from the field to cooling, transportation, value-added processing, cold storage, and transportation before reaching the retail or foodservice distribution center, retail/foodservice outlet or retail/foodservice/processing/preparation, and consumers. Leafy greens that are not field cored may enter the value-added processing and cooling step to be processed into fresh-cut products before entering the retail chain. Note: Figure 2 is reprinted from the “Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain” (Ref. 7). (Reprinted with permission). The designation as “raw agricultural

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commodity” or “fresh-cut” in the figure or discussion is not a determination by FDA regarding the characterization of the product for regulatory purposes, such as the applicability of 21 CFR part 110.

IV. Definitions

The following definitions apply to this guidance:

Adequate means that which is needed to accomplish the intended use in keeping with good practice.

Clean means that food or food-contact surfaces are washed and rinsed and are visually free of dust, dirt, food residues, and other debris.

Control means to manage the conditions of an operation in order to be consistent with established criteria, and to follow correct procedures.

Control Measure is any action or activity that can be used to prevent, reduce, or eliminate a microbiological hazard.

Current Good Manufacturing Practices (CGMPs) refer to the CGMP regulations that are found in 21 CFR 110 (Current Good Manufacturing Practices in Manufacturing, Processing, Packing, or Holding Human Food).

Environmental Assessment means an evaluation of the growing environment, taking into consideration factors including topography, hydrology, geographical features, climatic conditions, land history, near-by land use, agricultural water, and domestic animal and wildlife presence to evaluate any safety risks that may affect the potential for leafy greens to be contaminated. Environmental assessments may be conducted prior to planting, during production, and immediately prior to harvest.

Facilities are the buildings and other physical structures used for, or in connection with, the harvesting, washing, sorting, storage, packaging, labeling, holding, or transporting of fresh produce.

Food-Contact Surfaces are those surfaces that contact fresh produce and those surfaces from which drainage onto the produce or onto surfaces that contact the produce may occur during the normal course of operations. “Food-contact surfaces” include equipment, such as containers and conveyor belts, which contact fresh produce, whether used in harvesting, post-harvesting, or packaging operations. “Food-contact surfaces” do not include items such as tractors, forklifts, hand trucks, and pallets that are used for handling or storing large quantities of contained or packed fresh produce and that do not come into actual contact with the food.

Fresh-cut fruits and vegetables or fresh-cut produce refer to fresh fruits and vegetables for human consumption that have been minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing, prior to being packaged for use by the consumer or a retail establishment (e.g., pre-cut, packaged, and ready-to-eat salad mixes). Fresh-cut produce does not require additional preparation, processing, or cooking before consumption, with the possible exception of washing or the addition of salad dressing, seasoning or other accompaniments.

For different commodities, the fresh-cut form may vary. For example, the form of fresh-cut leafy greens may be shredded, chopped, or uncut, while the fresh-cut form of carrots may be peeled and cut into julienned sticks or baby carrots.

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GAPs Guide refers to the guidelines set forth in the “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,” which was issued by FDA in 1998.

Hazard means a biological, chemical, or physical agent that is reasonably likely to cause human illness or injury in the absence of its control.

Human Pathogen means a microorganism capable of causing disease or injury to people. This is different from a plant pathogen which may cause disease to plants.

Nontransporter means a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Operator means the person or persons who have day-to-day responsibility for the production, harvesting, washing, sorting, cooling, packing, processing, shipping, or transportation of leafy greens, and responsibility for management of all employees who are involved in each of these activities.

Packinghouse means a facility where raw agricultural commodities are washed, trimmed or sorted and packed in commercial containers, e.g., cartons or totes.

Pest means any animal or insect of public health importance including birds, rodents, cockroaches, flies, and larvae that may carry pathogens that can contaminate food.

Raw Agricultural Commodity (RAC) means any food in its raw or natural state, including all fruits and vegetables that are washed, colored, or otherwise treated in the uncut natural form prior to marketing.

Ready-to-eat (RTE) describes foods that need no further preparation (e.g., washing or cutting) before eating.

Risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard or hazards in food.

Sanitary Survey is an inspection of the entire water system, including water source, facilities, and equipment, for the purpose of identifying conditions that may result in microbial contamination.

Spring Mix is a blend of baby lettuces, mustards, chards, spinach and chicories that will vary based on availability of supply.

V. Production and Harvest

A. Environmental Assessments and Risk Reduction Practices

An environmental assessment is intended to identify any food safety issues in the environment in and around the produce field that may increase the risk of contaminating the crop with pathogens. An environmental assessment evaluates topography, hydrology, geographical features, climatic conditions, land history, near-by

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land use, and domestic and wildlife presence.

FDA recommends:

- Conducting environmental assessments prior to the first seasonal planting, within one week prior to harvesting, and during harvesting operations.
- Assessing near-by land use and waterways for activities or conditions that may pose a risk of contamination such as livestock, wildlife, landfills, sewage treatment, chemical plants, or other conditions.
- Determining land history to identify microbial and chemical contamination from previous land use.
- Evaluating the risk to subsequent crop production on production acreage that has experienced recent postharvest grazing of domesticated animals.
- Evaluating production field locations and proximity to wildlife especially if the production field is isolated from other non-contiguous production areas, for example in foothill locations near open lands.
- Evaluating whether heavy rains or irrigation practices may increase the likelihood of soil-to-leafy greens contamination.

Practices FDA recommends to reduce the risk of microbial contamination of leafy greens in the production environment include:

- Locating production sites (to the degree feasible) to minimize potential access by wildlife. For example, considering the proximity to water, wildlife harborage, open range lands, non-contiguous production lots or blocks, and urban centers.
- Controlling risks associated with production fields that are encroached upon by urban development.
- Considering risk factors including septic tank leaching and domestic animal fecal contamination of production fields and harvest equipment.
- Exercising care to reduce the potential for windborne soil, water or other media that may be sources of contamination to come into contact with the edible portions of leafy greens.
- Monitoring and minimizing domestic animal and wildlife activity in leafy greens fields and production environments (e.g., reducing potential harborage and standing water, and utilizing animal repellants and attractants).
- Considering whether or not to harvest any portions of a field affected by unusually heavy wildlife activity or evidence of wildlife activity (e.g., presence of wildlife feces).
- Assessing the field at the time of harvest to ensure that no new food safety risks have occurred.
- Using harvest practices such as removing outer soiled leaves and not harvesting whole soiled heads of leafy greens when excessive soil or mud builds up on leafy greens.
- Training harvest employees to recognize and report for appropriate action any evidence of wildlife activity or infestations (e.g., feces).

B. Water

Water used in production and harvest operations may contaminate leafy greens if it contains human pathogens and contacts edible portions of leafy greens or transmits pathogens by means of water-to-soil and soil-to-leafy greens contact (Ref. 9). In addition, irrigation methods vary and each method may have varying potential to

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introduce human pathogens or promote human pathogen growth on leafy greens.

FDA recommends:

- Preparing a description of the irrigation water system. Using maps, photographs, drawings, or other means to communicate the location of permanent fixtures and the flow of the water system (including any water captured for re-use). Documenting permanent fixtures, including wells, gates reservoirs, valves, returns and other above-ground features that make up a complete irrigation system, so as to enable location on the field. Documenting water sources and the production sites they may serve.
- Performing a sanitary survey prior to the use of water in agricultural operations to determine if the quality of water meets applicable State and local requirements, and then monitoring water quality with regular testing.
- Evaluating irrigation methods (e.g., drip irrigation, overhead sprinkler, and furrow) for their potential to introduce, support or promote the growth of human pathogens on leafy greens. Considering issues such as the potential for irrigation methods to deposit soil on the crop or cause pooled or standing water that attracts animals.
- Considering the impact of storm events on surface waters used to irrigate crops. Bacterial loads in surface water are generally much higher after a storm than normal and caution should be exercised when using these waters for irrigation.
- Considering the potential for pathogen contamination and growth when combining water from different sources (e.g., water systems that convey untreated human or animal waste should not be combined with conveyances used to deliver irrigation water).
- Storing irrigation pipes and drip tape in a manner that reduces potential pest infestations and developing procedures to ensure safe use of irrigation pipes and drip tape if a pest infestation does occur.
- Ensuring that water used on harvesting equipment or during harvesting is of appropriate microbial quality for its intended use. Testing the water source regularly to ensure that it is of appropriate microbial quality for its intended use.
- Evaluating risks of using reclaimed (primary or secondary) water, including use in operations such as road dust abatement. Reclaimed water may be subject to State and local requirements.

Crop Protection Sprays (Pesticides)

It is important to be familiar with and follow all applicable requirements for crop protection sprays. Note that certain chemicals that are not required to be registered with EPA as pesticides may be regulated by FDA as food-contact substances.

FDA recommends:

- Ensuring that water used for spray applications of pesticides, particularly if used close to the time of harvesting, is not contaminated and is of sufficient microbial quality for this purpose. Note that many chemicals in crop protection sprays do not reduce or eliminate any pathogens present in the water used to mix the sprays.
- To ensure that water is of appropriate quality for its intended use, obtaining water from an appropriate source, or treating and testing water on a regular basis and as needed to ensure appropriate quality.

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- Having crop protection sprays applied by trained and, where applicable, licensed personnel.
- Developing Standard Operating Procedures (SOPs) for crop protection spray applicators, application equipment, storage, and usage (including handling, mixing, and diluting).
- Ensuring that the use of pesticides complies with all EPA requirements and any other federal, state and local requirements, including following approved directions for use on labeling.
- Maintaining and keeping current records of use of crop protection sprays.
- Storing crop protection sprays properly and securely. Disposing of empty containers according to the label/labeling and regulatory requirements.
- Ensuring that loading, diluting, and mixing of crop protection sprays is done in a manner that will not contaminate the water source or leafy greens.
- Ensuring that the cleaning of crop protection spray equipment is done in a manner that will not contaminate the water source or leafy greens.
- Following precautions to protect against contamination of leafy greens, food-contact surfaces, and packaging materials when mixing or applying crop protection sprays.

C. Soil Amendments

Soil amendments may be incorporated into agricultural soils used for leafy greens production to add organic and inorganic nutrients to the soil as well as to reduce soil compaction. Soil amendments can contain animal manure or can be composed primarily of plant materials. Soil amendments that contain animal manure are of concern because human pathogens may persist in animal manure (particularly aged manure or inadequately composted soil amendments) for weeks or months (Refs. 10, 11) and even longer under certain conditions (Refs. 12-14). Proper composting of animal manures via thermal treatment will reduce the risk of potential human pathogen survival. However, the persistence of human pathogens in agricultural soils depends on many factors such as pH, temperature, soil type, and native microflora and continues to be under extensive investigation (Refs. 15-18). Leafy greens may be contaminated through contact with contaminated soil amendments if soil amendments containing human pathogens are applied after plant emergence. Field soil contaminated with human pathogens may also provide a means of leafy greens contamination. Therefore, establishing suitably conservative pre-plant intervals, appropriate for specific regional and field conditions, is an effective step towards minimizing risk (Refs. 19, 20).

FDA recommends:

- Refraining from use of raw animal manure with any leafy greens crop.
- Refraining from using biosolids as a soil amendment for any leafy greens crop.
- Verifying that any soil amendment that does not contain animal manure has documentation (e.g., ingredient list, statement of identity, or letter of guaranty) from the producer or seller stating that it is manure free.
- Implementing management plans which ensure that the use of soil amendments will not pose a significant potential human pathogens hazard (e.g., timing of applications, storage location, source and quality, and transport).
- Verifying the time and temperature process used during the composting process to ensure that the potential of human pathogens being carried in the composted materials is reduced, controlled, or eliminated as applicable to regulatory requirements.

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- Maximizing the time interval between the soil amendment application and time to harvest.
- Implementing practices that reduce, control, or eliminate likely contamination of leafy greens fields that may be in close proximity to on-farm stacking of manure.
- Using soil amendment application techniques that control, reduce, or eliminate the likely contamination of surface water or edible crops being grown in near-by fields.
- Segregating equipment used for soil amendment applications such as compost or using effective means of equipment cleaning and sanitation before subsequent use.
- Minimizing the proximity of wind-dispersed or aerosolized sources of contamination (e.g., water and manure piles) that may potentially contact growing leafy greens or near-by edible crops.
- Obtaining compost from commercial suppliers that maintain temperature monitoring and turning records.
- Obtaining compost from commercial suppliers that have and provide documentation of written standard operating procedures (SOPs), to prevent cross-contamination of finished compost with raw materials through equipment, runoff, or wind.

D. Machine Harvest

This section addresses harvest and harvest aid equipment used for leafy greens that will be further processed into a ready-to-eat (RTE) product. Mechanical or machine harvest has become increasingly prevalent and provides opportunities for increased surface contact exposure. This includes field-cored lettuce operations that use various harvest equipment and aids.

FDA recommends:

- Establishing appropriate measures that reduce, control, or eliminate the potential introduction of human pathogens at the cut surface during and after mechanical harvest operations.
- If re-circulated rinse or antioxidant solutions are used on the cut surface, ensuring that they do not become a source of contamination.
- Using equipment that is designed to facilitate adequate cleaning and sanitation.
- Establishing the frequency of equipment cleaning and sanitation by developing sanitation standard operating procedures (SSOPs) and a cleaning and sanitation schedule for machine harvest operations.
- Using cleaning verification methods for harvesting equipment such as ATP (adenosine triphosphate) test methods.
- Locating equipment cleaning and sanitizing operations away from product and other equipment to reduce the potential for cross-contamination.
- Establishing equipment storage and control procedures that minimize the potential for contamination when the equipment is not in use. Establishing policies and sanitary design options that facilitate frequent and thorough cleaning and sanitizing of food contact surfaces.
- Developing and implementing appropriate cleaning, sanitizing, storage, and handling procedures of all food contact surfaces to reduce, control, or eliminate the potential for microbial cross-contamination (e.g., food contact surfaces may include transportation tarps and conveyor belts).

E. Hand Harvest – Contact with Soil During Harvest

After manual harvest of leafy greens, placing or stacking product on soil before the product is placed into a

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container may expose the product to human pathogens if the soil is contaminated. Research has demonstrated that microbes, including human pathogens, can readily attach to cut leafy greens surfaces (Ref. 21).

FDA recommends:

- Evaluating appropriate measures that reduce, control, or eliminate the potential introduction of human pathogens through soil contact at the cut surface after harvest (e.g., frequency of knife cleaning and sanitation, not placing cut surfaces of harvested product on the soil, container cleaning and sanitation, and using single use container lining).
- Avoiding stacking soiled bins filled with product on top of each other.

F. Transfer of Human Pathogens by Field Workers, Visitors, and Other Field Personnel

Leafy greens are handled by harvest crews during harvest. Persons working with produce in the field may transfer microorganisms of significant public health concern. Workers may not show signs of having an infectious disease but may still be infectious.

FDA recommends:

- Using appropriate preventive measures outlined in the GAPs Guide such as training in appropriate and effective hand washing, glove use, and mandatory use of sanitary field latrines to reduce, control, or eliminate potential contamination.
- Establishing programs that can be used to verify employee compliance with company food safety policies.
- Establishing a policy prohibiting eating, drinking, chewing gum, and using tobacco in leafy greens fields except in clearly designated areas.
- Posting conspicuous signs that communicate food safety policies and food safety principles. Using signs that are multilingual, pictorial, or both, as appropriate to the workforce.
- Providing drinking water with either fountain or single use containers. Handling drinking water containers in a manner that prevents them from becoming a source of contamination.
- Establishing a policy restricting employees from wearing visible jewelry in the field.
- Ensuring that employees, visitors, and other field personnel wear clean and suitable outer garments. Considering, as appropriate to the operation, using hair restraints, plastic aprons and sleeves, restricting nail polish or false nails, and requiring empty pockets above the waist.
- Establishing a policy that employees, visitors, and other field personnel with open sores, cuts, burns, boils, or similar conditions report the condition to a supervisor before working or entering the leafy greens field.
- Establishing a policy that encourages supervisors to observe symptoms of infectious disease and reassign workers as appropriate.
- Establishing a policy that encourages employees to notice and report symptoms of infectious disease.
- Optimizing the location and sanitary design of the field latrines and hand wash facilities to facilitate the reduction, control, or elimination of human pathogens from employees' hands. Evaluating the location of field sanitation and worker hygiene facilities to maximize accessibility and use, while minimizing the potential for the facility to serve as a source of contamination.

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- Establishing a sufficient frequency of facility maintenance/cleaning and sanitation.
- Establishing equipment storage and control procedures that minimize the potential for contamination when the equipment is not in use.
- Establishing policies and sanitary design options that facilitate frequent and thorough cleaning and sanitizing of food contact surfaces (e.g., policies that prohibit employees from removing tools such as knives from the work area and require the use of knife scabbards that can be easily cleaned and sanitized).
- Minimizing the harvesting of leafy greens with visible signs of decay or damage due to the possible increased risk of the presence of human pathogens. Either removing the decayed or damaged portions or not using the leafy green.

Gloves

If leafy greens are handled with bare hands, hand washing procedures should be documented. If gloves are utilized, a procedure for glove use should be established, followed, and documented.

Disposable Gloves

If disposable gloves are used, FDA recommends:

- Using single use disposable gloves for hand contact with leafy greens.
- Washing hands before putting on gloves.
- Using hand sanitizers only after proper washing of hands.
- Changing disposable gloves after returning from meals, smoking, using toilet facilities, any process involving handling of materials other than leafy greens, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.

Reusable Gloves

If reusable gloves are used, FDA recommends:

- Using gloves made of materials that can be readily cleaned and sanitized.
- Ensuring that gloves are adequately washed and sanitized.
- Issuing appropriately cleaned and sanitized gloves, regularly and as necessary. For example, cleaning and sanitizing, or changing reusable gloves after meals, smoking, using toilet facilities, or any process involving handling of materials other than leafy greens where the gloves may become torn, soiled, or otherwise damaged or contaminated.
- Providing a safe and sanitary location (e.g., bin or shelf) to leave gloves when they are not in use by an employee (e.g., during breaks and toilet use).
- Training workers to clean and sanitize or change gloves that have come in contact with the ground or other non-food contact surfaces.

G. Equipment Facilitated Cross-contamination

Farm equipment that has contact with soil, soil amendments, or water that is likely to contain

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microorganisms of significant concern to public health may spread microbial contamination to other production lands or water sources. Equipment that may come into contact with raw untreated manure, untreated compost, waters of unknown quality, wildlife or domestic animals and other potential human pathogen reservoirs is of particular concern. Higher risk activities may entail the use of this equipment in proximity to, or in areas where it may contact edible portions of leafy greens.

FDA recommends:

- Identifying any field operations that may pose a risk for cross-contamination.
- Segregating equipment that is used in high-risk operations.
- Using effective means of equipment cleaning and sanitation before subsequent equipment use in leafy greens production, if it was previously used in a high-risk operation.
- Developing appropriate means of reducing, controlling, or eliminating the possible transfer of human pathogens to soil or water that may contact edible portions of leafy greens through use of equipment.

H. Flooding

Flooding (flowing or overflowing of a field with water outside a grower's control) may contaminate crops that are in close proximity to soil, such as leafy greens, if there is contact between flood water or contaminated soil and the edible portions of leafy greens (Refs. 22, 23). Pooled water (e.g., after rainfall) that is not reasonably likely to cause contamination of the edible portions of fresh produce is not considered flooding.

In a November 4, 2005, FDA ["Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce,"](#) the Agency stated as follows:

FDA considers ready to eat crops (such as lettuce) that have been in contact with flood waters to be adulterated due to potential exposure to sewage, animal waste, heavy metals, pathogenic microorganisms, or other contaminants. FDA is not aware of any method of reconditioning these crops that will provide a reasonable assurance of safety for human food use or otherwise bring them into compliance with the law. Therefore, FDA recommends that such crops be excluded from the human food supply and disposed of in a manner that ensures they do not contaminate unaffected crops during harvesting, storage or distribution. Adulterated food may be subject to seizure under the Federal Food, Drug, and Cosmetic Act, and those responsible for its introduction or delivery for introduction into interstate commerce may be enjoined from continuing to do so or prosecuted for having done so . . . [F]ood produced under insanitary conditions whereby it may be rendered injurious to health is adulterated under section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)).

Situations related to flooding can be separated into three groups: (1) a product that has come into contact with flood water, (2) a product that is in proximity to a flooded area but has not come in contact with flood water, and (3) a production field which was partially or completely flooded in the past before a crop was planted. The recommendations for each situation are provided below.

For a product that has come into contact with flood water, FDA recommends:

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- Excluding such crops from the human food supply and disposing of them in a manner which ensures they do not contaminate unaffected crops during harvesting, storage or distribution.

For a product that is in proximity to a flooded area but has not come in contact with flood water, FDA recommends:

- Preventing cross-contamination between flooded and non-flooded areas (e.g., cleaning equipment and eliminating contact of any farming or harvesting equipment or personnel with the flooded area during production and harvest of crops in non-flooded areas).

For formerly flooded production ground, FDA recommends:

- Assessing field history and crop selection.
- Determining the time interval between the flooding event, crop planting, and crop harvest.
- Determining the source of flood waters (e.g., drainage canal, river, or irrigation canal) and whether there are significant upstream potential contributors of human pathogens.
- Allowing soils to dry sufficiently and be reworked prior to subsequently planting crops on formerly flooded production ground.
- Sampling previously flooded soil for the presence of microorganisms of significant public health concern or appropriate indicator microorganisms. Note: Microbial soil sampling can provide valuable information regarding relative risks, but sampling by itself does not guarantee that all raw agricultural commodities grown within the formerly flooded production area are free of the presence of human pathogens.

I. Water Usage to Prevent Product Dehydration

Leafy greens may be sprayed with small amounts of water during machine harvest or in the field container just after harvest to reduce product water loss. Water used in harvest operations may contaminate leafy greens if it contains human pathogens and contacts edible portions of leafy greens.

FDA recommends:

- Testing this water periodically to ensure that it is of appropriate microbial quality for its intended use.
- Establishing and implementing cleaning and sanitation schedules for containers and equipment that will be used in hydration.
- Establishing policies for the storage and control of water tanks and equipment used for hydration operations to minimize the potential for contamination when such equipment is not being used.

J. Greenhouse Production

For the purposes of this guidance, a greenhouse is presumed to be enclosed. Note that the recommendations in this section do not apply to shade houses or other open structures. Shade houses and other open structures should follow recommendations on field production and harvesting.

1. Greenhouse

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FDA recommends:

- Utilizing a foot dip station at all entrances or other measure to prevent the introduction of harmful microorganisms or agents. Documenting the sanitizer used and monitoring to ensure sanitizers are maintained at effective levels.
- Ensuring that soil or other growth medium used in the greenhouse is suitable for its intended purpose and does not pose a risk of contamination.
- Ensuring that adequate hand washing stations with single use towels are available. Using stations designed to drain or capture all waste water in a manner that does not pose a contamination hazard to the greenhouse.
- Posting conspicuous signs that communicate food safety policies and food safety principles. Using signs that are multilingual, pictorial, or both, as appropriate to the workforce.
- Maintaining covered trash cans in adequate number and location.

2. Grounds

Operator-Controlled Grounds

The grounds about a greenhouse under the control of the operator should be kept in a condition that will protect against contamination of leafy greens.

FDA recommends:

- Properly storing equipment, removing litter and waste, and cutting weeds and grass within the immediate vicinity of the facility because these may constitute an attractant, breeding place, or harborage for pests.
- Maintaining roads, yards, and parking lots so that they do not present a risk of contamination in areas where leafy greens are exposed.
- Adequately draining areas that may contribute to the risk of contamination of leafy greens by seepage, foot-borne filth, or providing an animal attractant or breeding place for pests.
- Operating systems for waste treatment and disposal in an adequate manner so that these systems do not present a risk of contamination in areas where leafy greens are exposed.

Grounds Outside of Operator Control

If the greenhouse grounds are bordered by land that is not under the operator's control and those grounds are not maintained in the manner described above, care should be exercised by the greenhouse operator to assess and mitigate the effects of pests, dirt, and filth that may present a risk of contamination. Potential hazards include livestock, wildlife, landfills, and sewage treatment plants. Although hazards may originate from land that is outside of operator control, there are mitigation measures that may be within the control of the operator.

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- Conducting an environmental assessment (e.g., considering topography, land history, near-by land use, domestic animal and wildlife presence) as appropriate to the operation, of the surrounding land use and the environment.
- Taking appropriate control measures to minimize any potential food safety hazards, which may include using berms, fences, ditches, buffer zones or other strategies to effectively mitigate any hazards.
- Establishing and maintaining records of the assessment, results, and any mitigation measures used to minimize hazards.

3. Pest Control

Rodents, Birds, Amphibians (e.g., Tree Frogs), Reptiles, and Other Facility Pests

FDA recommends:

- Taking effective measures to exclude pests from the greenhouse and protecting against the contamination of leafy greens by pests.
- Ensuring that the use of insecticides or rodenticides is consistent with applicable requirements and that precautions are followed to protect these products from contaminating leafy greens, food-contact surfaces, and packaging materials.
- Ensuring that no domestic or other animals are permitted in areas where leafy greens are grown, packed, handled, or stored.

Crop Protection Sprays (Pesticides)

It is important to be familiar with and follow all applicable requirements for crop protection sprays. Note that certain chemicals that are not required to be registered with EPA as pesticides may be regulated by FDA as food-contact substances.

FDA recommends:

- Ensuring that water used for spray applications of pesticides, particularly if used close to the time of harvesting, is not contaminated and is of sufficient microbial quality for this purpose. Note that many chemicals in crop protection sprays do not reduce or eliminate any pathogens present in the water used to mix the sprays.
- To ensure that water is of appropriate quality for its intended use, obtaining water from an appropriate source, or treating and testing water on a regular basis and as needed to ensure appropriate quality.
- Having crop protection sprays applied by trained and, where applicable, licensed personnel.
- Developing Standard Operating Procedures (SOPs) for crop protection spray applicators, application equipment, storage, and usage (including handling, mixing, and diluting).
- Ensuring that the use of pesticides complies with all EPA requirements and any other federal, state and local requirements, including following approved directions for use on labeling.
- Maintaining and keeping current records of use of crop protection sprays.

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- Storing crop protection sprays properly and securely. Disposing of empty containers according to the label/labeling and regulatory requirements.
- Ensuring that loading, diluting, and mixing of crop protection sprays is done in a manner that will not contaminate the water source or leafy greens.
- Ensuring that the cleaning of crop protection spray equipment is done in a manner that will not contaminate the water source or leafy greens.
- Following precautions to protect against contamination of leafy greens, food-contact surfaces, and packaging materials when mixing or applying crop protection sprays.

K. Documentation and Records

As a general practice, it is important that firms that produce and harvest leafy greens maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J. Note: Farms (as defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J.

Operational records about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors of contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices, field, facility and vehicle cleaning and sanitation, and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of water sources and use; testing water quality; treating water; monitoring for signs of animal intrusion; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, the location of the field and location in the field, if applicable, and the activity being monitored in the documentation.

Product tracing refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product between its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its source. Effective product tracing systems can serve as an important complement to food safety programs intended to prevent microbial contamination.

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FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA [“Guide To Traceback Of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations”](#) (June 2006) (Guide to Traceback Investigations) to develop a product tracing system applicable to the leafy greens supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

VI. Postharvest

A. Cooling

Leafy greens are routinely cooled immediately after harvest by forced-air cooling, vacuum cooling (e.g., iceberg lettuce) or spray-vacuum (hydrovac) cooling (e.g., leaf lettuce, romaine lettuce, spring mix, and spinach). Water used in postharvest operations may contaminate leafy greens if it contains human pathogens and contacts edible portions of leafy greens.

FDA recommends:

- Obtaining leafy greens from suppliers that follow GAPs and the recommendations in this guidance.
- Establishing a procedure for inspecting and accepting or rejecting incoming loads of leafy greens.
- Ensuring that incoming documentation provides sufficient information to facilitate product tracing and establishing a system to maintain that documentation.
- Ensuring that water used to hydrovac cool leafy greens is of appropriate microbial quality for its intended use.
- Using single-pass or one-use cooling water in hydrovac cooling of leafy greens.
- Using water disinfectant at sufficient levels if leafy greens hydrovac cooling water is re-circulated, and monitoring the disinfectant levels to reduce the potential risk of cross-contamination.
- Cleaning and sanitizing cooling equipment on a regular basis to ensure that the potential for cross-contamination is minimized.
- Developing and implementing appropriate cleaning and sanitizing procedures for all food contact surfaces to reduce, control, or eliminate the potential for microbial cross-contamination.
- Developing SSOPs for equipment, including procedures and a schedule for the cleaning and sanitation of cooling facilities.
- Establishing policies and sanitary design options that facilitate frequent, thorough cleaning and sanitizing of equipment and food contact surfaces.
- Evaluating layout and drainage issues associated with the cooling facility to prevent cross-contamination of equipment that may be returned to the field.
- Implementing pest control procedures to minimize potential for introduction of human pathogens.
- Ensuring that product placement and storage do not facilitate cross-contamination (e.g., pallets placed on top of bins or iced containers placed above containers with non-iced product).

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- Taking appropriate actions to ensure that near-by land use does not pose a significant risk of product cross-contamination.
- Ensuring employees are trained regularly regarding food safety and hygiene.

B. Water

Water used in post-harvest operations may contaminate leafy greens if it contains human pathogens and contacts edible portions of leafy greens. Consider all uses of water and ice where they contact leafy greens (e.g., ice placed on the top of leafy greens to chill the product and water used to facilitate packing whole leaf lettuces into plastic bags).

FDA recommends:

- Assessing the vulnerability of each water source and distribution system to potential pathogen contamination.
- Testing the water source with sufficient frequency.
- Testing the water as close to the point-of-use as practical.
- Ensuring that tanks that hold or store water used in packing operations are included in relevant cleaning and sanitation schedules.
- Ensuring that rinse water disinfectant levels are monitored and adjusted to adequate levels to prevent cross-contamination and ensuring that only approved wash-water disinfectants are used.

C. Re-Use of Field Containers

Re-use of field containers (such as bins or totes) provides the potential for product cross-contamination if they are not stored, transported and re-used in a sanitary manner. Accordingly, field containers should be cleaned and handled in a manner that minimizes the potential for microbial contamination.

FDA recommends:

- Developing appropriate cleaning, storage, and handling procedures (e.g., standard operating procedures (SOPs)) for re-usable field containers to reduce, control, or eliminate the potential for microbial cross-contamination and ensure that they are stored, transported and re-used in a sanitary manner.
- Using single-use liners with containers which cannot be sanitized. Not reusing liners.
- Not using containers that have or show evidence that they have been infested by pests.
- Implementing procedures for storing and handling single-use containers such as corrugated boxes and pallets that reduce, control, or eliminate the potential for pest infestation.
- Removing from food contact use broken or damaged containers that are not easily cleaned. If they are retained for other uses (e.g., trash), clearly marking them for their intended use.

D. Bulk Bin Modified Atmosphere Process (MAP)

Leafy greens may be packed in bulk bins and placed under a modified atmosphere (e.g., reduced oxygen atmosphere) for shipment to processing plants. Equipment and handling procedures employed in MAP bins have the potential for introducing human pathogens.

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One example of a resource that contains detailed information regarding procedures for handling bulk bin MAP leafy greens is “[Field Cored Lettuce Best Practices](#)” prepared in April 2001 by the National Food Processors Association, International Fresh-cut Produce Association, and United Fresh Fruit & Vegetable Association. Please note that FDA is not responsible for the content of the document, which FDA has not verified.

FDA recommends:

- Developing appropriate equipment and handling procedures so that packing of leafy greens bulk bins in a modified atmosphere is conducted in an environment that is protected from potential food safety hazards.

E. Condition and Cleaning and Sanitation of Transportation Vehicles

Whole and fresh-cut leafy greens may be transported to the cooling and cold storage facilities by numerous modes of transportation. Transportation of leafy greens should be managed to reduce, control or eliminate the risk of contamination.

FDA recommends:

- Transporting whole and fresh-cut leafy greens in shipping containers and vehicles that are clean and sanitary.
- Implementing inspection and evaluation management programs for shipping containers and trailers to verify that they are clean and sanitary.

F. Employee Hygiene

Leafy greens may be handled by employees in cooling and cold storage facilities. Employees working with produce in a cooler or cold storage facility may transfer microorganisms of significant public health concern. Therefore, employee hygiene and sanitary procedures are appropriate in all environments where produce and people are in proximity.

FDA recommends:

- Using appropriate preventive measures outlined in the GAPs Guide such as training in appropriate and effective handwashing, glove use, and mandatory use of sanitary facilities to reduce, control, or eliminate potential contamination.
- Prohibiting eating, drinking or smoking outside of designated areas to reduce the potential for product contamination.
- Optimizing the location and sanitary design of toilets and handwashing facilities to facilitate the control, reduction, or elimination of human pathogens from employee hands. Evaluating the location of worker hygiene facilities to maximize accessibility and use, while minimizing the potential for the facility to serve as a source of contamination.
- Establishing a sufficient frequency of toilet and handwashing facility maintenance, cleaning, and sanitation.
- Establishing equipment and supply storage and control procedures that minimize the potential for contamination when equipment and supplies are not being used.

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- Establishing policies and sanitary design options that facilitate frequent and thorough cleaning and sanitizing of food contact surfaces.

Gloves

If leafy greens are handled with bare hands, hand washing procedures should be documented. If gloves are utilized in post harvest activities, a procedure for glove use should be established, followed, and documented.

Disposable Gloves

If disposable gloves are used in handling leafy greens, FDA recommends:

- Using single use disposable gloves for hand contact with leafy greens.
- Washing hands before putting on gloves.
- Using hand sanitizers only after proper washing of hands.
- Changing disposable gloves after returning from meals, smoking, using toilet facilities, any process involving handling of materials other than leafy greens, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.

Reusable Gloves

If reusable gloves are used, FDA recommends:

- Using gloves made of materials that can be readily cleaned and sanitized.
- Ensuring that gloves are adequately washed and sanitized.
- Issuing appropriately cleaned and sanitized gloves, regularly and as necessary. For example, cleaning and sanitizing, or changing reusable gloves after meals, smoking, using toilet facilities, or any process involving handling of materials other than leafy greens where the gloves may become torn, soiled, or otherwise damaged or contaminated.
- Providing a safe and sanitary location (e.g., bin or shelf) to leave gloves when they are not in use by an employee (e.g., during break and toilet use).
- Training workers to clean and sanitize or change gloves that have come in contact with the ground or other non-food-contact surfaces.

G. Documentation and Records

As a general practice, it is important that firms involved in postharvest operations relating to leafy greens maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The regulation requires, among other things, that records maintained by nontransporters include an “adequate description” of the food, including brand name and specific variety, and provides an example of

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"romaine lettuce, not just lettuce." The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J.

Operational records about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or employee training, may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors of contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices, facility and vehicle cleaning and sanitation, and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of water sources and use; testing water quality; treating water; monitoring for signs of animal intrusion; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

Product tracing refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product from its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its source. Effective product tracing systems can serve as an important complement to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the leafy greens supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

VII. Fresh-Cut/Value-Added Processing

Fresh-cut processors are reminded that FDA's regulations in 21 CFR part 110 establish CGMPs for preparing, packing or holding food. The CGMP regulations include both binding requirements and non-binding recommendations relating to personnel, buildings and facilities, equipment, and production and process controls. Part 110 uses the word "shall" to state mandatory requirements and the word "should" to state recommended or advisory procedures. Fresh-cut fruits and vegetables, including fresh-cut leafy greens, are considered "processed food" as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(gg)). Thus fresh-cut processors of leafy greens are subject to the CGMP regulations. The practices provided in this guidance, including those applicable to fresh-cut processors,

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are recommendations that complement, but do not supersede, the requirements and recommendations in part 110.

A. Receiving

FDA recommends:

- Obtaining leafy greens from suppliers that follow GAPs and the recommendations in this guidance.
- Establishing a procedure for inspecting and accepting or rejecting incoming loads of leafy greens.
- Ensuring that incoming documentation provides sufficient information to facilitate product tracing and establishing a system to maintain that documentation.

B. Wash Water

Fresh-cut leafy greens go through one or more vigorous washing processes before they are packaged and sold to consumers. Wash water disinfectants can be very effective in eliminating free-floating or exposed microorganisms. However, chlorine and other wash water disinfectants are used in wash systems to prevent the potential for cross-contamination, not to sanitize produce surfaces. Washing RTE leafy greens during fresh-cut processing is necessary but does not ensure that fresh-cut produce is free of microbes.

Scientific studies have demonstrated that washing produce in cold, chlorinated water may reduce microbial populations but not eliminate them. Microbial reduction on leafy greens surfaces is a disinfectant concentration-by-time dependent relationship. Human pathogens, if present on the surface of leafy greens, may not be completely eliminated by washing. This is because microorganisms adhere to the surface of produce and may be present in nooks and crannies where water and wash water disinfectants cannot penetrate. Microorganisms, including human pathogens, have a greater affinity to adhere to cut surfaces than uncut surfaces.

Water used in the washing of fresh-cut leafy greens may become a source of contamination if it contains human pathogens and contains insufficient wash water disinfectant. When leafy greens are fully submerged in water, for washing or as a means of cooling, they are more likely to have wash water infiltration into the tissues. Growing conditions, particularly conditions such as soil type (e.g., sand or muck), may have a profound effect on wash water disinfectant effectiveness as well as the potential for removal of soil particles (e.g., difficulty in removing sand particles from crinkly leaf spinach products).

FDA recommends:

- Ensuring that single-pass water used to wash leafy greens after cutting is of appropriate microbial quality for its intended use.
- Ensuring that sufficient concentrations of approved water disinfectant are present to reduce the potential for leafy greens-to-water-to-leafy greens cross-contamination when water used to wash leafy greens after cutting is re-circulated or reused. Monitoring the disinfectant level in the water at a frequency sufficient to ensure that it is of appropriate microbial quality for its intended use.
- Minimizing use of leafy greens for fresh-cut production which have visible signs of decay or damage because of the possible increased risk of the presence of human pathogens. Either removing the decayed or damaged portions or not using the leafy green.

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- Evaluating water quality variables such as pH, organic load, turbidity, soil, and product throughput capacity, to ensure that the wash water disinfectant used is effective in reducing the potential for water-to-leafy greens cross-contamination.
- Evaluating process design to accommodate raw product variability (e.g., variations in soil and weather conditions) that may affect wash water efficacy. For example, evaluating specific product wash water disinfectant demand, product-to-water volume ratio; assessing use of filtration systems to remove sand or soil from water during processing; or assessing when water should be changed or added.

C. Labeling of Leafy Greens for End Users

End users, including consumers, may have difficulty in quickly and easily differentiating a leafy green which should be washed before consumption from an RTE food product that need not be washed again before consumption.

FDA recommends:

- Clearly labeling products to avoid end user confusion regarding whether or not a product needs to be washed before consumption. For example, labeling fresh-cut products as "washed," "triple washed," or "ready-to-eat" on the package to indicate that there is no need to wash the product prior to consumption.

D. New Technologies

New technologies that enhance production, quality or commercial distribution may have unforeseen consequences for food safety. For example, technologies that significantly extend product shelf-life may allow extra time for the survival, persistence and slow growth of human pathogens from very low (undetectable) levels to levels that may be capable of causing disease, particularly if temperature abuse occurs.

FDA recommends:

- Determining the impact on food safety when evaluating new technologies, e.g., shelf-life extenders.

E. Finished Product Packaging

Appropriate primary and secondary packaging is the last protection of RTE products against subsequent contamination with undesirable microorganisms.

FDA recommends:

- Determining whether the primary and secondary packaging operations are sufficient to prevent subsequent contamination.
- Determining whether the packaging manufacturer understands the ultimate use of the package.
- Appropriately labeling packages that do not provide a barrier to potential external microbial contamination to indicate that the leafy greens are not RTE.

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F. Documentation and Records

As a general practice, it is important that firms involved in fresh-cut/value added processing operations for leafy greens maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The regulation requires, among other things, that records maintained by nontransporters include an “adequate description” of the food, including brand name and specific variety, and provides an example of “romaine lettuce, not just lettuce.” The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J.

Operational records about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or employee training, may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors of contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices, facility and vehicle cleaning and sanitation, and employee training programs.
- Maintaining records for significant activities performed, such as testing water quality and disinfectant level; monitoring storage temperatures; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

Product tracing refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product from its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its source. Effective product tracing systems can serve as an important complement to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the leafy greens supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

VIII. Distribution

Firms involved in distribution operations relating to leafy greens are reminded that FDA's regulations in part 110 establish CGMPs for preparing, packing or holding food. The practices provided in this guidance, including those applicable to firms involved in distribution operations, are recommendations that complement, but do not supersede, the requirements and recommendations in part 110. Establishments engaged solely in the harvesting, storage, or distribution of one or more RACs, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public; however, generally are not subject to the requirements of part 110, as provided in 21 CFR 110.19.

A. Condition and Sanitation of Transportation Vehicles

Whole and fresh-cut leafy greens can take many routes to the end user, including direct or indirect shipments through intermediate distributors and warehouses. It is important to manage each step of each route to reduce, control, or eliminate the risk of microbial contamination.

FDA recommends:

- Transporting whole and fresh-cut leafy greens in shipping containers and trailers that are clean and sanitary.
- Implementing inspection programs of shipping containers/trailers to verify that food safety needs are being met. Evaluating items including the container/trailer condition, overall cleanliness of the walls and floor, good structural condition (e.g., free from damage to walls, floor, or ceiling, such as exposed insulation and holes), absence of off-odors or unusual smells, and functional chilled air delivery chute.
- Addressing food safety requirements for the sanitary transportation of leafy greens in contracts with transportation companies. For example, establishing restrictions on previous cargoes to avoid the possibility of cross-contamination.

B. Condition and Sanitation of Distribution/Cooling Facilities

Cooling facilities used to hold product during distribution may serve as a point of contamination if appropriate practices are not followed.

FDA recommends:

- Establishing and implementing good handling practices as appropriate to the product and stage of distribution (e.g., written cleaning and sanitation procedures, pest control, and food safety training for workers).

C. Techniques for Temperature Measurement of Product

Leafy greens are perishable products and proper temperature control during distribution is critical for optimal shelf-life and product quality and safety. Monitoring product temperature by invasive techniques (i.e., puncturing the package with a temperature probe) can be a source of product contamination.

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FDA recommends:

- Using non-invasive techniques for monitoring product temperature, e.g., “pillowing” the temperature probe between two packages.
- Discarding any product or package that is penetrated if an invasive technique is used.

D. Documentation and Records

As a general practice, it is important that firms involved in distribution operations relating to leafy greens maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. See § 1.352 in FDA’s regulations for further information on the types of records transporters must maintain. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J.

Operational records about products and practices can be helpful to firms. First, such records help ensure consistency of distribution operations. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or employee training, may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors of contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs in areas such as vehicle cleaning and sanitation and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of storage temperatures; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

Product tracing refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product from its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its source. Effective product tracing systems can serve as an important complement to food safety programs intended to prevent microbial contamination.

FDA recommends:

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- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the leafy greens supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

IX. Retail and Foodservice

Specific procedures for storing and displaying food, for excluding or restricting ill employees, for washing hands, date-marking, and for washing and sanitizing equipment can be found in the [FDA Food Code](#). The FDA Food Code is a model code developed by FDA to assist and promote consistent implementation of national food safety regulatory policy among the local, State, and tribal governmental agencies that have primary responsibility for the regulation or oversight of retail level food operations. Further considerations for leafy greens are found below. In addition, handlers of leafy greens should be aware of and follow all Federal, State, and local requirements. Leafy greens may be handled extensively at retail or in food service operations; therefore, it is of particular importance to wash hands thoroughly with soap and water before cutting or handling leafy greens and to rewash hands as necessary.

A. Retail and Foodservice Handling

Leafy greens may be contaminated by numerous means in the field-to-fork supply chain. Important considerations at the retail and foodservice level include excluding or restricting ill food workers, ensuring appropriate employee hygiene/handling, using water of adequate quality, and preventing cross-contamination.

FDA recommends:

- Considering not using leafy greens with visible signs of decay or damage, due to the increased risk of the presence of human pathogens. Decayed or damaged leafy greens and lesions caused by plant pathogens may act as harborage for human pathogens (Ref. 24). When in doubt about the use of decayed or distressed product, either removing the unusable portions or not using the leafy greens.
- Utilizing information in the [FDA 2005 Food Code Section 3-302.15](#), which specifies: "Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form." Not rewashing packaged produce labeled "ready-to-eat," "washed" or "triple washed."
- Ensuring water used to wash leafy greens is of appropriate microbial quality for its intended use.
- Rewashing, after cutting, the leafy greens in a clean and sanitized sink or container. Immersing and agitating the cut leafy greens, then removing from water while avoiding contact with any dirt or debris that may settle out. Repeating the cleaning process as needed with a clean and sanitized basin, sink, or bowl and fresh water.
- Cleaning and sanitizing all food-contact equipment and utensils that contact cut leafy greens (e.g., cutting boards and knives) with the following steps: washing thoroughly with hot soapy water, rinsing, sanitizing, and air-drying.
- Washing hands thoroughly with soap and water before cutting or handling leafy greens and rewashing hands as necessary.
- Using a barrier such as gloves and/or an appropriate utensil changed with sufficient frequency to

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prevent cross-contamination to touch fresh-cut leafy greens. Note: This does not alleviate the need for proper hand-washing.

- Storing and displaying fresh-cut leafy greens under refrigeration throughout distribution to enhance the safety and quality of the product.
- Storing and displaying fresh-cut leafy greens under refrigeration to minimize bacterial growth and delay deterioration of the product.
- Establishing a policy for fresh-cut leafy greens prepared at retail/foodservice for how long the refrigerated product can be displayed and offered for sale. Marking the product, with “prepared on” or “best if used by” date.
- Following manufacturer instructions for the product such as “keep refrigerated” or “best if used by.”
- Developing training programs that will educate all potential handlers of leafy greens in retail and food establishments regarding the importance of food safety and the recommendations in this guidance.

B. Labeling of Leafy Greens for End Users

End users may have difficulty in quickly and easily differentiating a leafy green that should be washed before consumption from an RTE food product that does not need to be washed again before consumption. In addition, end users should note that the shipment of RACs, including leafy greens products, often have little protection from cross-contamination because they are simply packed in a primary container such as a box.

FDA recommends:

- Reading labels carefully to determine whether a product should be washed before consumption (e.g., hearts of romaine) or is an RTE product (e.g., fresh-cut salad) that does not need to be washed again before consumption.
- Thoroughly washing leafy greens in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in RTE form.
- Remembering that there is no need to wash fresh-cut leafy greens again if they are labeled as “washed,” “triple washed,” or “ready-to-eat” on the package. Although not recommended, if end users do re-wash RTE fresh-cut leafy greens, having appropriate sanitary washing and drying conditions in the foodservice, retail or in-home food preparation environment to reduce the potential for cross-contamination of fresh-cut RTE produce with human pathogens. Washing produce in food preparation areas that have clean and sanitary food contact surfaces (e.g., colanders, knives, and drying cloths), clean and sanitary preparer hands, and an environment clearly segregated from other food items (e.g., raw meat and poultry) that may harbor human pathogens.
- Ensuring that storage practices do not subject the product to potential cross-contamination (e.g., not storing raw meats above leafy greens cartons). Note: Packaging for leafy greens that are not RTE such as whole heads of lettuce in boxes or spinach leaves in plastic bags labeled “wash before use” is not designed to provide a sufficient barrier to cross-contamination.

C. Leafy Greens Re-Crisping

Leafy greens such as lettuce may be re-crisped by placing the whole or fresh-cut product in containers with tap water. The small amounts of chlorine present in the tap water may be quickly inactivated by the organic load

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presented by leafy greens. This may increase the potential for leafy greens cross-contamination particularly if additional leafy greens are added to the re-crisping container (Ref. 25).

FDA recommends:

- Reducing the potential for water and utensils to contaminate leafy greens when re-crisping leafy greens by cleaning and sanitizing the sink or container before re-crisping and using water supplies that meet drinking water standards for re-crisping. Changing the water at a frequency sufficient to ensure that it is of appropriate microbial quality for its intended use.
- Evaluating use of running water to re-crisp leafy greens as needed, in lieu of re-crisping by water soaking, to reduce the potential for cross-contamination.

D. Documentation and Records

As a general practice, it is important that retail and foodservice firms handling leafy greens maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, “Establishment, Maintenance, and Availability of Records,” already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J. Note: Restaurants and certain retail food establishments (as those terms are defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J.

Operational records about products and practices can be helpful to firms. First, such records help ensure consistency of handling and/or preparation activities and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or employee training, may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors of contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of storage temperatures; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
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production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product from its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its source. Effective product tracing systems can serve as an important complement to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the leafy greens supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

X. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

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